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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,623	12/07/2001	John Kung	JBP 576	9719
27777	7590	05/20/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			SHARAREH, SHAHNAME J	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/020,623	Applicant(s) KUNG ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-26, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/19/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment filed on February 19, 2004 has been entered. Claims 28, 29 are under consideration. Claims 24-26 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Any rejection that is not addressed in this Office Action is considered obviated in view of the amendments.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 28, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farng et al US Patent 5,643,584 in view of Simon et al US Patent 5,730,972 and Patel US patent 4,863,970.

Farng teaches methods of improving retinoid penetration comprising compositions comprising a retinoid (recited in Farng as a tretinoin), a polyoxyethylene alcohol surfactant such as polyethylene glycol glyceryl stearate, an antioxidant such as ascorbic acid, and an acrylic polymer such as a carbopol. (see col 2, lines 5-35; col 5, lines 1-20; examples 1-5; claim 19). Farng explicitly encourages the use of surfactants in amounts effective to enhance penetration of retinoid into skin. (see col 2, lines 7-10). The concentrations of each such components of Farng fall within the ranges of the instantly claimed components. Farng only fails to use ascorbic acid-2-glucoside.

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Simon teaches that saccharides derivatives of ascorbic acid such as ascorbic acid glucosides are highly water-soluble and are converted to Vitamin C when administered to skin to provide the same function as the ascorbic acid. (see col 2, lines 51-60). Therefore, ascorbic acid glucoside is considered to be a functional art recognized equivalent to Ascorbic Acid for at least topical administrations. Further, Simon teaches topical formulations of ascorbic acid glucoside with an acrylate polymer such as pemulen and polyethylene glycols such as polyethylene glycol stearate. (see col 7-9, examples 3-4).

Patel is only provided to set forth that polyoxyethylene alcohols are well-recognized surfactants with penetration enhancing properties and are readily used in the art to improve skin permeation of drugs in topical formulations. Accordingly many polyoxyethylene alcohols are enumerated in this patent including oleyl alcohol, glycerol monoleate etc... (see abstract; col 4, lines 56-67; col 6, lines 1-60).

Accordingly, since ascorbic acid of Farnig and ascorbic acid glucoside of Simon are viewed to be functional art equivalents, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute ascorbic acid of Farnig with the ascorbic acid glucoside of Simon, because substituting art recognized equivalents for purposes of providing a same function is *prima facie obvious*. The ordinary skill in the art would have had a reasonable expectation of success in observing the same functions employing ascorbic acid glucoside of Simon as Ascorbic acid of Farnig.

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Further, absence of showing unexpected results employing any art equivalent polyoxyethylene surfactant as enumerated in Patel and encouraged by Farnig would have been well within purview of one of ordinary skill in the art.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action, because the scope of the claims has been modified. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahn timer Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RUSSELL TRAVERS
PRIMARY EXAMINER